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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,318	11/07/2001	Erik Leonard Hoffman	05032-00011	4521

7590 07/31/2006

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EXAMINER

COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/037,318		HOFFMAN, ERIK LEONARD	
	Examiner		Art Unit	
	David Comstock		3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,25-35,37-51 and 53-72 is/are pending in the application.
- 4a) Of the above claim(s) 1-23,25-33,37,45-50,55 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34,35,38-44,51,53,54 and 57-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34, 35, 38-44 and 58-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yapp (0 099 167; cited by Applicant).

Yapp discloses a fastening element 12 comprising a supporting element 24, a hollow pin 13, and fixing means 28. (See Figs. 1-7.) The supporting element has a bottom surface 22 that abuts sawn-off bone 42 and a top surface 26 that is flat and parallel to the bottom surface. The supporting element is thus plate shaped and also extends on at least two sides beyond an outer longitudinal edge of the pin (see Figs. 3 and 4). The angle between the longitudinal axis of the pin and the bottom surface of the plate is at approximately a 90 degree angle. The supporting element further comprises a coupling element 32 on a side remote from the pin. The pin extends from the supporting element into bone 42. The pin is at an angle with respect to a main surface of the supporting element (see Fig. 4). The pin is not symmetrical with respect to the longitudinal axis but rather is rectangular in cross section (see Figs. 3 and 4 and page 5, lines 2-5). The pin has a finish, i.e. porous bone contact surfaces 20, 22, to promote bone ingrowth into the hollow pin (see Figs. 1, 4, and 7 and page 3, lines 23-26). After

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the bone ingrowth has occurred, both the outside and inside surfaces of the pin are in contact with bone tissue. The fixing means fixes the fastening element in position wherein the pin extends into bone. The fixing means comprises a screw 28 that screws into the pin from the side remote from the supporting element. The screw adjusts the tension of the fixing means. Yapp does not disclose the angle between the longitudinal axis of the pin and the bottom surface of the plate between about 125 and 145 degrees or the angular offset of the coupling element with respect to the longitudinal axis of the pin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an angle between the longitudinal axis of the pin and the bottom surface of the plate between about 125 and 145 degrees and to provide an angular offset, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum *or workable* ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. It is noted that Applicant has not defined "largely" with sufficient specificity to preclude an interpretation of the pin of Yapp being "largely" hollow, since Yapp shows a pin with a hollow portion and the degree or ratio of hollow space has not been defined. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001), and MPEP 2111.01.

Claims 51, 53, 54, 57 and 67-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masini (5,571,203)

Masini discloses a method of sawing a femur on a cut line 230 to create an abutment surface that extends at right angles to a load axis of a joint (see Figs. 2-4 and 6 and col. 6, lines 35-65). The hollow pin 312 of a fastening element 442 is driven into a hole formed in the bone such that a supporting element 226, to which the pin is attached, abuts the abutment surface. The supporting element has a bottom surface 228 and a top surface that is flat at least at its periphery and parallel to the bottom surface. The pin is driven in at a 90 degree angle with respect to the surface. The device is fixed from a remote side through cortical bone by a pin 250 introduced through cortical bone 214 and fixed to the device at a connection 234. Masini does not disclose the angle between the longitudinal axis of the pin and the bottom surface of the plate between about 125 and 145 degrees or the angular offset of the coupling element with respect to the longitudinal axis of the pin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an angle between the longitudinal axis of the pin and the bottom surface of the plate between about 125 and 145 degrees and to provide an angular offset, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or *workable* ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant's arguments in the Request for Continued Examination filed 15 May 2006 have been considered but are not persuasive.

In response to Applicant's argument that neither Yapp nor Masini render obvious the claimed invention, it is noted that the test for obviousness is not whether the noted features may be bodily incorporated into the prior art device to arrive at the claimed subject matter, but simply what the references as a whole make obvious to one of ordinary skill in the pertinent art. Both Yapp and Masini disclose the general conditions or elements of the claimed invention, as set forth in the rejection. Where these references may be lacking--for example, the particular angle of the pin with respect to the plate--such parameters would merely involve routine skill in the art to determine, as already set forth in the rejection. With regard to Yapp, it is noted that the office action does not state that the angle between the longitudinal axis of the pin and the bottom surface is 90°, but rather, generally and broadly states that the portions are separated by "approximately a 90 degree angle." It is noted that the figures in Yapp make very clear that the angle may be greater than 90 degrees (see, e.g., Figs. 3-5). Furthermore, even though Yapp shows such an angle, the device is manifestly still capable of having the pin emerge just below the trochanter, with the bolt 28 being threaded into the shaft at this desired location. Thus, on its face, the reference does not in any way teach against angles greater than 90 degrees. Moreover, Applicant's argument that altering the angle would necessarily prevent the shaft and bolt from being correctly located with respect to the femur is not persuasive. It is noted that many conditions alone or in

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combination affect where the shaft and bolt would emerge, including varying or differing patient anatomy, length, depth and location of the cut made in the femur (which also depends on varying patient anatomy), length of the pin, etc. Thus, in order to address the particular exigencies of a given surgical scenario, it would be obvious to provide the pin at an angle as set forth in the rejection, with the pin still being disposed in the suitable location. It is noted that the ability to tailor the device to best fit the patient is a stated aim of Yapp (see, e.g., page 3 line 27 - page 4, line 10). Likewise, with regard to Masini, disposing the pin at an angle as set forth in the rejection, would not necessarily even affect the cortical bone as, again, the ultimate location of the pin depends on many factors including varying patient anatomy and length, depth, location, orientation of the cut made in the femur, length of the pin, and so forth. It is further noted that the cut line 230 is "approximately at right angles to the load axis of the joint" as claimed by applicant (emphasis added). As noted by applicant, the difference between the femoral longitudinal axis and the load axis may be as little as 6 degrees (or up to 12 degrees), and applicant has not defined the permissible scope or range of angles that are encompassed by the qualifier "approximately." In the absence of any such special definition, it is reasonable and appropriate for the examiner to apply art that appears to satisfy applicant's invention, as claimed.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

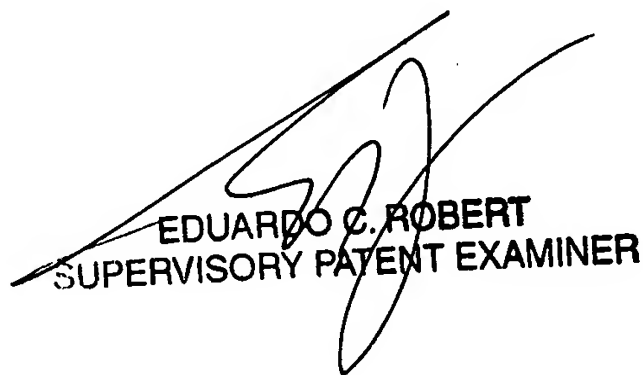
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



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